REMARKS

Claims 3-5, 9-12, 34, 39 and 62 are pending in the application. No new matter has been added.

Rejection of Claims 3-5, 9, 10-12, 34, 39, and 62 Under 35 U.S.C. 112

The Examiner has rejected claims 3-5, 9-12, 34, 39 and 62 under 35 USC 112, first paragraph failing to comply with the written description requirement. The Examiner is of the opinion that Applicants' claims "read on a specific cancer, ovarian cancer, while the support Applicants point out broadly references cancer, essentially any type of cancer." Applicants respectfully traverse this rejection.

Reading the specification in its entirety it is clear that the cancer samples being evaluated are ovarian cancer samples, and not samples from any type of cancer. Beginning on page 42 of the specification, Applicants describe the samples used in the identification of the biomarkers used in the methods of the invention. Specifically, Applicants teach:

> A total of 80 specimens were used in this study. Blood samples were collected from 42 patients at the Johns Hopkins Hospital with sporadic ovarian serous neoplasms prior to tumor resection. These ovarian tumors included 11 FIGO-stage I, 3 FIGO-stage II and 28 FIGO-stage III patients. The median age of these patients was 53 years (range: 36 to 84). Specimens from 38 women without known neoplastic diseases were used as controls. The median age of the controls was 57 years (range: 45 to 75). Specimens, collected in EDTA, Vacutainer tubes, were centrifuged at 2,000 rpm for 20 min and plasma samples were harvested to avoid leukocyte contamination. Specimens obtained prior to 2000 were analyzed for CA 125II using Centocor CA125II assays (Fujirebio Diagnostics, Malvern, PA). For the remaining specimens, CA125 levels were measured in either serum or EDTA plasma using the Tosoh AIA-PACK CA125 assay on the 600 II analyzer (Tosoh Medics, South San Francisco, CA). The Centocor CA125II assay is equivalent to the Tosoh CA125 assay (unpublished data). The Tosoh CA125 assay is approved for use in serum, however the assay was validated for plasma in house and results for serum and plasma were determined to be equivalent. Results

were available in 68 out of the 80 total specimens. The median, mean and standard deviation of CA125 for the cancer group (n=32) were 58U/mL, 174.8U/mL, and 256.5U/mL, respectively, and for the control group (n=36), 7.6U/mL, 7.8U/mL, and 8.9U/mL, respectively.

Among the total plasma samples (n=80), a group of 67 patients (29 ovarian cancer and 38 non-cancer cases) were initially analyzed for biomarker selection and identification. We then repeated the analysis on the entire collection of 80 specimens to include more early stage patients. Statistical analysis of biomarker performance was done based on the entire 80 patients. (Emphasis added).

Therefore, based on the teachings of the specification, it is clear that the cancer being detected is ovarian cancer and not any type of cancer as the examiner has asserted. The specification as a whole teaches that the biomarkers identified as having altered expression of biomarkers of ovarian cancer, as the cancer samples are isolated from subjects having been diagnosed with ovarian cancer.

Based on the foregoing, Applicants assert that the amendments previously made to the claims do not constitute new matter. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

The Examiner further believes that the specification does not teach "wherein an increase in the levels of one or more of Markers II and III, or a decrease in the levels of one or more of Markers I, IV, V or VII is indicative that the subject has ovarian cancer." Applicants disagree. Applicants point the Examiner's attention to Example 1, page 47 of the application. The results of Example 1 clearly indicate that "at 9.2kD, 19.8kD, and 60kD showed higher expression levels on average among the specimens from the cancer patients compared to the controls while the remaining peaks demonstrated the inverse expression pattern." The marker of 9.2kD is Marker II and the marker of 19.8kD is Marker III.

Moreover, the paragraph bridging page 5 and page 6 of Applicants' specification teaches that:

[p]referred methods for detection and diagnosis of cancer comprise detecting at least one or more protein biomarkers in a subject sample, and; correlating the detection of one or more protein biomarkers with a diagnosis of cancer, wherein the correlation takes into account the detection of ***one or more biomarker in each diagnosis, as compared to normal subjects, wherein the one or more protein markers are selected from***:

Marker I: having a molecular weight of about 8.6 kD
Marker II: having a molecular weight of about 9.2 kD
Marker III: having a molecular weight of about 19.8 kD
Marker IV: having a molecular weight of about 39.8 kD
Marker V: having a molecular weight of about 54 kD
Marker VI: having a molecular weight of about 60 kD
Marker VII: having a molecular weight of about 79 kD.

wherein one or more protein biomarkers are used to diagnose cancer.

As indicated above, Applicants specification teaches that one or more of Markers I-VII can be used in the methods of the invention to diagnose ovarian cancer. Therefore, the claims as pending directed to methods of using six of Markers I-VII are supported by the specification as filed. Based on the foregoing, Applicants assert that the amendments previously made to the claims do not constitute new matter and respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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